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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FAY SHARPE LLP 1100 SUPERIOR AVENUE, SEVENTH FLOOR CLEVELAND, OH 44114				
EXAMINER				
JOYNER, KEVIN				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/809,094

Applicant(s)

CASTELLINI, FRANCO

Examiner

KEVIN C. JOYNER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 9, 10 and 12-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 9, 10 and 12-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date _____
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2-6, 9, 10, 12-16 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castellini (U.S. Publication No. 2002/0033362) in view of Belfer et al. (U.S. Patent No. 6,142,170) and Behringer (WO 02/15811- English Equivalent U.S. Patent No. 7,056,472).

Castellini discloses an apparatus for sterilizing and sanitizing water circuits, of dental units that include a user fluid supply line (1) adapted to be connected, at one end to an associated mains water supply (2) and connected, at the other end to a first branch (3) of the dental unit for supplying a series of devices comprising a plurality of handpieces (5a-c); the apparatus comprising:

at least one first unit (17 & 24) containing a first disinfecting/sterilizing fluid connected to a third independent branch (16) for supplying the first fluid at least to the first branch by being connected to the first branch to permit performance of programmable discontinuous sterilization or sanitization cycles in the first branch;

a second unit (15 & 23) comprising a second container for holding a second sterile, disinfectant or medicinal fluid connected to the first branch and continuously supplying the second fluid to the first supply branch independently of, and as an alternative for, the user fluid from the supply line (paragraphs 18-20 and 25);

Control means (12) acting on at least one of the first and second units and designed to select the supply of the first or of the second fluid according to the operating configuration of the dental unit, said control means capable of selecting a continuous steady-state supply of the first branch with the second fluid or discontinuous sterilization/disinfection cycles of the first branch with the first fluid (paragraphs 9 and 36-38); and

That the first unit and control means act upon one another in order to provide a series of operable functions including the capability to provide a continuous supply cycle with the second fluid and a discontinuous sterilization or sanitization cycle with the first fluid.

Castellini does not appear to disclose that he second unit comprises a third container capable of holding a disinfectant or medicinal product to be mixed with the sterile liquid from the second container by respective dosing means acting between the two containers in such a way as to supply at least the first branch with the second fluid

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having properties suitable for the treatment to be carried out. Belfer discloses an apparatus for sterilizing and sanitizing water circuits of dental units comprising a user supply line and a first branch (146). The reference continues to disclose that the apparatus further comprises two containers (16 as shown in Figure 1) capable of holding a sterile liquid in one container and a disinfectant or medicinal product in the other container to be mixed with the sterile liquid by a respective dosing means acting between the two containers in such a way as to supply at least the first branch with a fluid having properties suitable for the treatment to be carried out (columns 6 & 7, lines 60-68 & 1-5; column 5, lines 50-60) in order to provide two disinfecting solutions to clean, disinfect, filter, and scrub the water lines in a dental system. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Castellini to include in the second unit two containers capable of holding a sterile fluid in one container and a disinfectant or medicinal product in the other to be mixed with the sterile liquid by a respective dosing means acting between the two containers in order to provide one uniform solution to perform two different tasks on a water line such as cleaning, disinfecting, filtering, and/or scrubbing as exemplified by Belfer.

Castellini does not appear to disclose that the apparatus comprises a product detection means capable of acting on the first unit and on the control means to enable activation of a continuous supply cycle when the second fluid is detected and a discontinuous sterilization cycle when the first fluid is detected. However, Behringer continues to disclose a product detection means capable of acting to enable activation

of a continuous supply cycle when a second fluid is detected and a discontinuous sterilization cycle when a first fluid is detected in order to provide the most effective disinfecting fluid to the water circuit at any given time in column 3, lines 30-65. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Castellini to include a product detection means capable of acting to enable activation of a continuous supply cycle when a second fluid is detected and a discontinuous sterilization cycle when a first fluid is detected in order to provide the most effective disinfecting fluid to the water circuit at any given time as exemplified by Behringer (For a more detailed explanation, please see the **Response to Arguments** section of this Office Action).

Regarding claims 3 and 6, the reference also discloses that the second unit is equipped with a second control and selection means (22) that is capable of enabling a continuous supply of the second fluid, when required, in the first branch and is synchronized with means (9v) that is capable of supplying a user fluid and with first means (8v) for supplying a first disinfecting/sterilizing fluid (paragraphs 25, 27, and 38). More specifically, as disclosed in paragraph 25, the second control means supplies the second fluid in an alternative fashion to the first fluid. Therefore, the first fluid must be stopped by the means for supplying the user fluid, and the means for supplying the disinfectant must be started to introduce the disinfecting fluid. For this process to occur, the elements must be synchronized to provide a fully functional apparatus. Concerning claim 4, Castellini discloses that the second unit that supplies the second fluid is connected directly to the first fluid supply branch (paragraph 25) as shown by the

branch labeled numeral 7 in Figure 1. With regard to claim 5, Castellini also discloses that the second unit that supplies the second fluid is connected to the third independent branch (16) leading into the first branch (3) as disclosed in paragraph 25 and shown in Figure 1.

Concerning claim 9, the reference continues to disclose that the first unit comprises at least one first container (17), holding the first fluid, and first means (19) for extracting the first fluid and introducing it into the third branch (16) in paragraphs 27-30. With regard to claim 10, the apparatus is fully capable of comprising the second fluid of a liquid mixed with a suitable product to produce a second sterile, disinfectant or medicinal fluid; the second container being removably connected, through a stable fastening element (18) equipped with second means (23) for extracting the second fluid mixture (paragraphs 18 and 27).

Regarding claim 12, the reference also discloses that the control means (12) comprises a logical selection unit connected to the first and second means that is capable of selecting the first or second fluid supply according to required operating elements, and designed to enable continuous supplying of the second fluid to each single handpiece selected or to perform cycles of predetermined length and with predetermined quantities of the first fluid in paragraphs 37-40. Concerning claims 13-15, the containers of Castellini are fully capable of holding the product in a liquid, powder, or granulated form.

Concerning claim 16, Castellini in view of Belfer is relied upon as set forth in reference to claim 11. All of the containers of Castellini are connected to a respective

cap (18) equipped with a cannula (20) for extracting the product as such is a commonly known system for extracting solutions. Belfer continues to disclose that the two containers of various types (column 8, lines 11-20) are connected through a respective conduit, to a branch for supplying the second container equipped with the dosing means as shown in Figures 2a-c. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a third container connected through a respective conduit, to a branch for supplying a second container equipped with a dosing means in order to provide one uniform solution to perform two different tasks on a water line such as cleaning, disinfecting, filtering, and/or scrubbing as exemplified by Belfer. It is noted that one of ordinary skill in the art that modifying the apparatus in Castellini with additional containers as shown by Belfer would provide the additional containers with caps and cannulas as required by Castellini.

Regarding claim 17, Castellini continues to disclose that the second control (22) is coordinated with the means (9v) that supply the fluid from the mains so as to allow the second container unit to introduce the second sterile disinfectant or medicinal fluid into the mains supply line. Castellini does not appear to disclose that the second fluid is simultaneously introduced into the mains fluid from the supply line. Behringer discloses an apparatus for sterilizing water circuits of dental units comprising a user fluid supply line connected to a mains water supply (3) and a dental unit (1) through a first branch (2). The apparatus continues to disclose that a second container unit (5) simultaneously introduces a second sterile disinfectant fluid into the mains fluid from the supply line in order to provide a system that sterilizes the water circuit while it is being

used (column 4, lines 33-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Castellini to allow the second container unit to simultaneously introduce the second sterile fluid into the mains fluid from the supply line in order limit any unnecessary down time that may be caused for sterilization purposes as exemplified by Behringer.

Regarding claims 18-23, that apparatus is fully capable of utilizing various mixtures of purified sterile water mixed with a disinfectant or medicinal product. Most notably, a liquid of 0.1% physiological saline solution and a disinfectant or medicinal product, hydrogen peroxide and water at a concentration of between 0.1-3%, Chlorhexidine and sterile water at a final concentration of between 0.002 and 0.2, and Triclosan and a liquid at a final concentration of between 0.005 and 0.5.

Terminal Disclaimer

4. The terminal disclaimer filed on January 1, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,612,838 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

5. Applicant's arguments filed October 15, 2007 have been fully considered but they are not persuasive.

Applicant's Principle arguments are:

(a) Castellini does not show or suggest a third container holding a disinfectant or medicinal product to be mixed with the sterile liquid. Moreover, Castellini does not disclose or suggest dosing means acting between the second container and the third container. It is also noted that Castellini fails to show or suggest product detection means acting on the first unit.

Castellini is not relied upon for these limitations. Belfer (U.S. Patent No. 6,142,170) and Behringer (WO 02/15811- English Equivalent of U.S. Patent No. 7,056,472) are relied upon for these limitations.

(b) Neither Castellini nor Belfer or Behringer disclose that the product detection means are capable to detect a fluid obtained by mixing two different liquids.

As disclosed by Behringer, a water supply (3) is provided wherein it passes through a sterilization unit (5) that provides a degerminating agent (column 4, lines 32-40). A means (16) is provided in order to determine the concentration and/or type of the degerminating agent and control the dosage of said agent to the treatment liquid (i.e. regulate the concentration of said agent; column 3, lines 35-50). As such, the means (16) is a product detection means that is fully capable of detecting a fluid obtained by mixing two different liquids (as the degerminating agent is fully capable of being applied to the treatment fluid in liquid form). Therefore, Behringer discloses a product detection means capable of detecting a fluid obtained by mixing two different liquids.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN C. JOYNER whose telephone number is (571)272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leigh McKane/
Primary Examiner, Art Unit 1797

KCJ